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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/725,623
Filing Date: December 01, 2003
Appellant(s): KAMRAVA, MICHAEL M.

Brent Vecchia
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/24/2010 appealing from the Office action mailed 11/24/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

U.S. Patent Application No. 10/080,177.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-18 and 26-34 are rejected.

Claims 19-25 are cancelled.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

| | | |
|---------------------------|--------|---------|
| U.S. Patent No. 4,474,576 | Gobby | 10-1984 |
| U.S. Patent No. 5,472,419 | Bacich | 12-1995 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 30 and 33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

When claim(s) recite(s) a device/apparatus with elements being "attached to" subject matter that is naturally occurring in nature, such recitation makes the claim(s) non-statutory.

In claims 30 & 33, the recitation **an embryo in the distal portion**.

These recitations positively claim non-statutory subject matter and it must be deleted or incorporated as a functional recitation in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

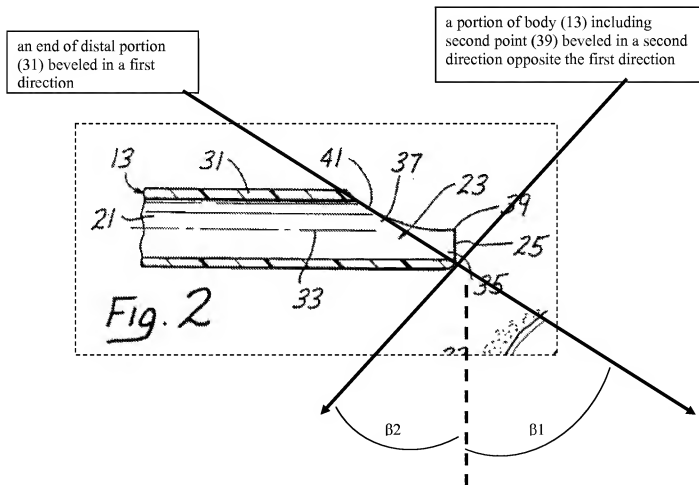
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over by (U.S. Patent No. 4,474,576) and further in view of Bacich (U.S. Patent No. 5472419).

Gobby discloses an artificial insemination a delivery member (30) comprising a delivery section (51), a storage section (53), and a passage through both sections (51, 53), the delivery member (30) defines a first axis of symmetry throughout the passage. Figure 2 illustrating a distal portion of the delivery member (30) is offset so as to preferably between 2 to 5 degrees inclined to the longitudinal axis of the delivery member (30), thus, the distal portion of the distal delivery section (31) defines a second different axis of symmetry throughout the passage a first axis of symmetry.

The Gobby device does not disclose the distal passage portion of the delivery section (51) is beveled.

Bacich discloses a transfer catheter body (13) comprising a proximal portion (27), a distal portion (31), an elongated passage (21), the distal portion (31) having an end that is beveled in a first direction across the passage (21) from one side to another, thereby, rendering the bevel in its direction across the opening, as recited, a portion of catheter (13) including a second point beveled in a second direction opposite the first direction defining a tip, showing by $\beta 1$ & $\beta 2$ below. See illustration below.



In view of Bacich, it would have been obvious to one skilled in the art during the time of this invention to modify the Gobby's distal passage portion of the delivery section (51) such that it would have a bevel, as such would facilitate the delivery process.

With regards to claims 1 and 11 reciting the material of the tip, the Bacich reference discloses the catheter body (13) is of polytetrafluoroethylene (PTFE) or other biocompatible, flexible material (column 4 lines 17-20), of which exhibits sufficient rigidity & sufficient flexibility.

With regards to claims 1 and 11 reciting the tip is shaped to be inserted into the endometrial lining of the subject, Figures 4 & 8 in the Bacich reference illustrates the tip of catheter body (13, 13a) is **shaped** to be inserted into the endometrial lining of the subject.

Regarding claims 2 & 3 and 14 & 15, particularly to claims 3 & 15 reciting the beveled opening angled between 10° to 15°, Figure 2 of Bacich illustrates such opening angle range.

Regarding claims 6 & 7 and 12 & 13, particularly to claims 7 & 13 reciting the second axis of symmetry differs by a deflection angle of 10 to 15 degrees from the first axis of symmetry, the Gobby's distal passage portion is deflected or offset from the longitudinal axis preferably by 2 to 5 degrees, however, the 10 to 15 degrees deflection is not out of the ordinary given the anatomy of each woman varies from person to person, one skilled in the art during the time of the invention would have modify the Gobby's offset range to be 10 to 15 degrees from the longitudinal axis as such would accommodate various uteral anatomy.

Furthermore, applicant's specification discloses in paragraph 0028 the preferred deflection 10 to 15 degrees but lacks the criticality for the claimed deflection. Thus, such recited

deflection falls within reasonable ranges, one skilled in the art would have considered such deflection ranges for purposes of optimizing the embryo delivery procedure.

With regards to claims 9 & 10 and 17 & 18, particular to claims 10 & 18 reciting the inner diameter of the tip is between approximately 400 and 500 micrometers, the Bacich reference discloses the diameter of the passage (21) is 0.5 millimeter or 500 micrometers, the diameter of the passage (21) is essentially inner diameter of the tip.

With regards to claims 26, 27, and 31, Figure 6 in the Gobby reference illustrates the distal portion of the delivery section (51) is pointed.

With regards to claim 28 & 32, the second point on the catheter body (13) beveling on the second direction (see illustration above) yields a refined edge, thus, serving as a cutting tool.

With regards to claim 29 & 34, Figures 6 in the Gobby reference illustrates the distal portion of the delivery section (51) defines a second different axis of symmetry throughout the passage a first axis of symmetry, rendering that distal portion of member (30) a microsurgical instrument for purposes of inserting into the endometrial lining.

With regards to claim 34, Figure 2 in the Bacich illustrates the angled/beveled distal opening (23) serves as a microsurgical instrument by delivering reproductive biological material (61) reproductive tracts (41).

(10) Response to Argument

Appellant's arguments filed on 11/24/2009 have been carefully considered but deemed not persuasive.

Regarding the rejection under 35 U.S.C. § 101, appellant argued that claims 30 & 33 do not claim the embryo but rather they claim the catheter having the embryo in the distal portion. In other words, appellant contends that the **embryo** itself is not being claimed but rather **a catheter having an embryo**. In response, the limitations "further comprises an embryo" in both claims 30 & 33 is a positive recitation of the embryo which is non-statutory matter. If those claims were not claiming the embryo, the claim limitations related to the embryo could be "the distal portion of the catheter is adapted to receive/hold an embryo" instead. This is not the case.

Regarding the 112 rejections, these rejected are withdrawn in view of appellant's comments.

Regarding the rejection under 35 U.S.C. § 103 to the Gobby/Bacich combination, appellant argued specifically that the Bacich reference does not teach **a portion of the shaft including the second point is beveled in the second direction opposite the first direction defining a tip shaped to be inserted into an endometrial lining of the subject**. Namely, appellant pointed out in Figure 2 of the Bacich reference that it has no tip and that a round surface does not meet the limitations in question. In response, the illustration as presented above clearly shows the tip. Namely, Figure 2 of the Bacich illustrates the rounded/curved surface to the even blunted end, a tangential line of a point on that rounded/curved surface a point of the shaft, that very point renders a tip, the even blunted end on one side of that point while the other

rounded/curved surface on the other side of that point rendering that very point the tip. As such, the Bacich discloses appellant's claimed tip.

Furthermore, the rounded/curved surface on the second length shown in Figure 2 of Bacich reference, is similar to that of appellant's round/curved surface shown in appellant's Figure 11. Therefore, the claimed limitations regarding the tip in appellant's claim 1 has not distinguished over the tip of Figure 2 in Bacich reference as presented in the rejection. Appellant remarked that the Bacich's distal end (25) is blunt and so it is not inserted into the tissue. In response, the distal end (25) was not interpreted as the tip. Appellant remarked that the Bacich's blunted tip not **shaped to be inserted into an endometrial lining of the subject**. Again, the blunted distal end (25) was not interpreted as a tip. Instead, the tip presented & illustrated above is shaped to be inserted into patient's endometrial lining. It is noted that claim 1 has not defined what the shape of the tip should be.

Regarding the Gobby/Bacich combination in 103 rejection, appellant argued specifically that the Bacich reference does not teach *the distal portion having an end that is beveled in a first direction across the opening, such that a length of the shaft to a first point on the end is a first length & a length of the shaft to a second point on the end is a second length longer than the first length, a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip*. In response, the limitation **the distal portion having an end that is beveled in a first direction across the opening, such that a length of the shaft to a first point on the end is a first length & a length of the shaft to a second point on the end is a second length longer than the first length**, so far, is defining the first point & the second point relative to the bevel across the opening. Figure 2 of Bacich meets

this limitation as illustrated above. The limitation **a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip** is also illustrated above. Appellant remarked that rejection relied on the lower right side of the rounded/curved surface in Figure 2 of Bacich as second point but the lower right side of the rounded/curved surface NOT at **“on the end” of the second length**. In response, claim 1 does not explicitly recites/defines the second point is **on the “distal” end of the second length**. Appellant remarked that the Bacich device is not intended and is not designed to **deliver an embryo within a flap of an endometrial lining**. In response, it is noted that claim 1 does not require such limitation.

Regarding the Gobby/Bacich combination in 103 rejection, appellant argued specifically that the Bacich reference does not teach *the tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject & sufficient flexibility to resist penetration of a uterine muscle of the subject*. The previous pointed out that Bacich discloses its catheter body (13) is of polytetrafluoroethylene, of which material is a type of polymers and is consistent with applicant's disclosure support (see specification paragraph 0027). Such material exhibits rigidity & flexibility in medical devices.

Regarding the Gobby/Bacich combination in 103 rejection under claim 11 reciting the distal portion having an angled tip, the previous rejection presented the Gobby reference comprising a delivery section (51) with its distal portion angled.

At least for reasons presented above, rejections presented in the Final Action are maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Camtu T. Nguyen/

Examiner, Art Unit 3772

Conferees:

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772

/Daniel G. DePumpo/

Primary Examiner, Art Unit 3700